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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/854,824

05/14/2001

Kristin J. Godbey

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12/16/2004

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EXAMINER

HOWARD, SHARON LEE

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,824

Applicant(s)

GODBEY ET AL.

Examiner

Sharon L. Howard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Applicant's arguments filed on 8/4/04 have been considered but are moot in view of the new grounds of rejection. Claims 40-50 have been cancelled. Claims 1-39 remain pending in this application.

DETAILED ACTION

Claim Rejections - 35 USC § 102's

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5,7-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Konishi (U.S. Patent No. 5,196,202).

Konishi teaches a sustained release dosage form (i.e. the oral cavity) comprising polymers consisting of acrylic copolymers and polyvinyl alcohol (see col.2, lines 47-57), a plasticizer (see col.2, line 64), including polyethylene glycol and other glycols, glycerin (see col.2, lines 58-68). Konishi teaches a drug impermeable layer which is formed between an adhesive layer (see Fig.1 and col.3, lines 39-46). Konishi teaches conventional drugs such as vitamins, antibiotics, and hormones which are known to be used for treating diseases of the oral cavity or for systemic use (see col.3, lines 14-27).

The drug impermeable layer may contain ethylcellulose, other cellulose derivatives, acrylic copolymers or other synthetic polymers (see col.3, lines 28-32). Konishi teaches that the adhesive layer comprises one or more water soluble polymers, a plasticizer and a water insoluble compound which forms a film (col.3, lines 33-38). See Example 4 at

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col.6 for the teaching of a three-layer film dosage form comprising a drug release control layer, a drug reservoir layer and an adhesive layer. Thus, the claims of Konishi meets the claims of the instant application.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,4,6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konishi ('202) in view of Bauer et al. (U.S. Patent No. 5,688,776).

Konishi is discussed above, but does not particularly teach arabinogalactan.

However, Bauer teaches arabinogalactan (see col.4) which is biodegradable (see the abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Konishi to include the particular

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carbohydrate, i.e. arabinogalactan, having the reasonable expectation of providing a dosage form which is known for the purpose of delivering a drug to a mammalian body.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-39 Are rejected under 35 U.S.C. 102(b) as being anticipated by Sieverding (U.S. Patent No. 4,750,482).

Sieverding teaches (See Fig.2), a hydrophilic, elastomeric, pressure-sensitive adhesive which could be used as a coating on a supportive web-like substrate for delivering an active agent (see col.17 lines 29-33, col.18, lines 28-57) and can be used as a cosmetic face mask. Examples of the pharmacologically active agents include analgesics, hormones and antirheumatics. Sieverding teaches that the adhesive may be used as a carrier for a depilatory agent (col.18, lines 54-57). The reference teaches that the adhesive may contain skin conditioners, perfumes, acne medication, antiperspirants, sunscreens, suntanning materials and humectants, thus providing continuous drug delivery to a mammalian body. The reference does teach polymers consisting of polyvinyl alcohol, monomers (col.9, lines 31-68, col.10-14), polyhydric alcohols such as glycerin and propylene glycol. Thus, the reference meets the claims of the instant application.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sharon Howard
December 13, 2004



THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600